Regulatory Unit Disposition of Senior Expert Review Assessment Recommendations -- September 1999

Background

The *Memorandum of Agreement for the Execution of Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors* (MOA), DOE/RL-96-26, signed in July of 1996, sanctions the concept of a Senior Expert Review (SER). Specifically, it states that the SER is comprised of three mature individuals "…highly experienced in safety and regulation…" that are individually available to the Manager of DOE-RL, and that provide the Manager with "…senior views of the radiological, nuclear, and process safety regulation of TWRS Privatization contractors." Task Order 9926 signed in July of 1999 between the Office of the Manager and the Technical Management Support Services Contractor, called for the provision of those senior views by William H. Young, Frank P. Baranowski and Robert M. Bernero of William H. Young & Associates, Inc. The focussed statement of work required the SER to "…assess selected Regulatory Unit approaches and processes for Part B-1 of the River Protection Project - Privatization contract, giving particular attention to their facilitation of thorough and timely safety decisions and reviews of safety documents."

Approach

In execution of the Task Order, the SER conducted detailed document review in mid-July 1999. During the last week in July, the SER made a site visit to receive briefings in areas of interest, observe a Topical Meeting and a Design Review, and interview selected Regulatory Unit (RU) personnel. A second site visit occurred in mid-August for follow-up and for interviews of senior officials of DOE-RL, DOE-ORP, and BNFL Inc. As an enclosure to an August 26, 1999, letter to the RL Manager, Mr. Young transmitted, on behalf of the SER, DRAFT *Report of an Assessment of the Regulatory Unit for the River Protection Project Privatization Contract*, and requested comments or needed changes. The Manager provided clarifying comments in a September 10, 1999, letter to Mr. Young, and the final SER assessment report was received on September 14, 1999.

Summary Results

In Section 1.2, “Summary Findings and Recommendations,” the SER states that "…The performance of the RU in planning and executing a first-of-a-kind regulatory concept was found to be exemplary:

- A well-thought-out regulatory process has been timely defined and is being effectively implemented.

- Top-level regulatory and safety requirements have been established and justified in a complete and timely manner.

- The RU and its plans and actions are well organized and executed, including the establishment of a good record of positions taken and their bases.

- A set of predictable regulatory requirements and expectations for their application is well along to being completed in a timely manner.

- The RU staff is highly competent and dedicated to making the regulatory approach and process work.

- The RU is proactive in seeking the early definition and resolution of safety issues and the development and application of subordinate standards tailored to the risk involved -- the graded approach to safety."

Recommendations and RU Disposition

In Chapter 4.0, "Assessment of the Regulatory Unit," the SER makes eleven separate recommendations for consideration by the Regulatory Official. These recommendations were based on observation of RU practices and processes. The SER did not report any concerns or findings of noncompliance. Their specific recommendations and the RU disposition of each follow:

SER Recommendation # 1. *The Regulatory Official should obtain the agreement of BNFL on a specific plan to submit any needed proposed changes to fundamental aspects of the design reflected in the ISAR in the same time frame that BNFL selects the design to be the basis for its Contract deliverables and the Part B-2 decision. As part of its evaluation input to the ORP, the RU should also be afforded the opportunity to review the BNFL April 2000 design deliverable -- in order to confirm the consistency of design information provided by BNFL to the RU and the ORP.*

RU Disposition: The SER raised the concern that RU tasking and the timing of regulatory actions is not synchronized with the DOE decision making process with regard to the award of the Part B-2 contract. Specifically, the SER noted that the RU would not receive the Preliminary Safety Analysis Report (PSAR) until after the scheduled date for the Part B-2 contract award. Additionally, the plant design submittal from BNFL that is scheduled to be delivered to DOE in April 2000 as an input to the Part B-2 contract decision is not formally scheduled for RU review. The April 2000 submittal is to be developed by BNFL on the basis of a design freeze that is to go into effect in January 2000. The SER made the above recommendation with regard to this concern.

BNFL will develop its financial proposal for the Part B-2 contract award based on a January 2000 design (design freeze), but as noted by the SER, design development will not stop in January 2000. The RU will continue the evaluation of BNFL progress in

addressing regulatory issues through Topical Meetings and the processing of Authorization Basis (AB) change requests through the remainder of the Part B-1 contract period. Per the SER recommendation, the RU will request BNFL to identify any additional AB changes, including proposed changes to the fundamental aspects of design, that will be required to support the April 2000 design.

The RU will prepare an evaluation of the BNFL readiness to proceed with Part B-2 of the contract based on all of the information available at the conclusion of Part B-1, including an evaluation of the consistency of regulatory assumptions with the April 2000 design deliverable. It is true that the PSAR is not scheduled to be submitted by BNFL until six months after the conclusion of Part B-1. However, at the conclusion of Part B-1, the RU will be in a position to evaluate BNFL's ability to submit an adequate PSAR based on almost two years of PSAR development as part of the Topical Meeting program.

The RU stays abreast of the evolving design by attending BNFL design review meetings. While not specifically required by the Contract to review the April 2000 design deliverable, the RU will review it to verify its consistency with the design information received in design reviews and Topical Meetings. Although the schedule for some of the very significant regulatory deliverables (e.g., the PSAR and the AB revisions) was not synchronized with contractual milestones, the RU will have developed considerable basis by the end of Part B-1 to make a recommendation with regard to the Part B-2 contract award.

SER Recommendation # 2. *The Regulatory Official should assure that the level of detail and degree of justification being required in AB approvals are appropriate and consider the stage of the project.*

RU Disposition: The SER made the above recommendation based on BNFL concerns that the RU is requiring an excessive level of detail and degree of justification for approving AB change requests. The RU recognizes that details and justification associated with AB change requests affect project costs and schedules. However, lack of adequate detail and justification will erode regulatory reliability and public confidence in the regulatory process. Given the regulatory program that has been established, the RU has latitude to balance the flexibility of the AB change process to optimize the program. Based on the SER recommendation, an evaluation of this aspect of the regulatory program was initiated.

The RU has met with BNFL several times to discuss this issue on both a management and a working level. Since the SER completed its evaluation, the RU has received several AB change requests from BNFL. These have served as working examples to evaluate regulatory requirements in terms of detail and justification against BNFL resource expenditures. Although BNFL has complained to both the SER and the RU of excessive justification requirements for AB change requests, it appears to the RU that resolution of these complaints is within BNFL’s control. The AB change requests that have been submitted have been voluminous, but generally have contained very little justification for

the actual changes being proposed. BNFL seems to interpret any RU request for justification as “excessive".

SER Recommendation # 3. *The Regulatory official should assure that the first-time application of risk-based integrated safety management techniques is addressed early in design development.*

RU Disposition: Risk-based integrated safety management (ISM) was included in the regulatory approach for TWRS-Privatization to permit the contractor to achieve adequate safety in an efficient and effective manner. The Contract embodies this regulatory approach by defining two risk-based, safety performance expectations -- dose-frequency standards for ensuring adequate control of the risk from individual hazardous events, and safety goals for ensuring adequate control of the collective risk from individual hazardous events considered together. The integration of risk-based safety into the design is being accomplished primarily through control of individual hazardous events in accordance with the process defined in the Contract (*DOE/RL-96-0004 Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization*).

Several activities have been undertaken or identified to ensure that the two risk-based, safety performance expectations are understood and are implemented in a complementary manner. They are as follows:

1. The implications of the risk goals that apply to workers were integrated into the review and approval of BNFL's dose-frequency standard for workers under accident conditions (Radiological Exposure Standards for Workers -- RESW) during Part A of the Contract. In effect, the dose-frequency standard was formulated to provide substantial consistency with the applicable risk goals.

2. BNFL has committed in its RU-approved Safety Requirements Document to perform risk analysis to ensure conformance with the risk goals of *DOE/RL-96-0006 Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors.* This analysis will be part of the Construction Authorization Request.

3. A Topical Meeting is scheduled for January 2000 to address the implications of and assessment methodology for collective risk. Working meetings between the RU and BNFL will be held, as appropriate, on this subject prior to the formal topical meeting.

4. The RU review guidance for the Construction Authorization Request addresses both of the risk-based, safety performance expectations. This guidance will ensure that the intended complementary perspective is clear, and that acceptable approaches to demonstrating conformance are articulated.

SER Recommendation # 4. *The Regulatory Official should assure that a minimum needed identification and consideration of safety issues is achieved in the Topical Meetings. The protocol should be revised, if necessary, to make such expectations and the appropriate focus in the subjects of the meetings clear.*

RU Disposition: The SER proposed this recommendation and the one following (SER Recommendation # 5.) in an effort to improve the conduct of Topical Meetings. The recommendations were based on a record review of a Topical Meeting on emergency planning that was held on May 25, 1999 and on the SER attendance at a meeting on the testing program for technology under development that was held on July 27, 1999.

The RU agrees with both recommendations concerning Topical Meetings, and implementing actions are already in effect. When the Topical Meeting protocol and schedule of topics were developed in August 1998, the primary objective for the meetings was to resolve issues that would require RU approval as part of the CAR review, but that had not been adequately addressed at the start of Part B-1. Based on the list of issues provided by the RU, BNFL was given the latitude to schedule the topics for Topical Meetings with the goal of resolving the issues prior to CAR submittal. The objective of this process was to preclude a delay in the start of construction due to an unacceptable CAR submittal. As the Topical Meetings progressed, it became evident that BNFL was falling behind in the development of resolutions for the scheduled topics and the likelihood of an adequate CAR submittal by the end of the year 2000 was decreasing proportionately.

From the RU perspective, the lack of progress in addressing issues culminated with the emergency planning meeting in May 1999. It became evident about two weeks prior to this Topical Meeting that BNFL had not started developing a draft emergency response plan for the CAR. The RU chose to proceed with the meeting, attempting to jump-start the emergency planning process, despite the lack of preparation on BNFL's part. The SER questioned the need for an emergency response plan this early in the process, however a draft emergency plan is a contract deliverable at the start of construction. Given the established emergency response organizations and capabilities in the Hanford area, as well as local requirements and the potential for sharing related resources, it is likely that development of the emergency response plan will affect associated PSAR sections. For example, since May 1999, interaction between BNFL and the Hanford Fire Department has resulted in BNFL abandoning the development of an independent fire fighting capability in favor of using local resources. Similar benefits are likely in areas of early warning, environmental monitoring, and meteorological requirements.

BNFL's inability to adequately address emergency preparedness and other topics in accordance with the 1998 schedule, caused the RU to reevaluate the Topical Meeting protocol and schedule before the SER arrived at Hanford. Meetings between the RU and BNFL resulted in a revised schedule of topics based on PSAR safety issues, with objectives and expectations for each meeting described in writing. Implementation of the above SER recommendation was initiated in May 1999 and is documented in a BNFL to RU letter dated July 12, 1999.

The SER noted that safety issues were absent from the discussions during the July Topical Meeting. The July Topical Meeting on Test Plans for Technology Under Development that was observed by the SER was actually a fill-in meeting while BNFL prepared to implement the newly developed schedule. Topical Meetings before and after July 1999 were and are focused on the more difficult safety issues that are associated with the PSAR.

SER Recommendation # 5. *The Regulatory Official should assure that differences between BNFL and the RU over the purpose to be achieved by and expected content of Topical Meetings are resolved, if possible, before the meetings are held. The BNFL suggestion* [to resolve issues in advance at a working level] *should be considered.*

RU Disposition: Working level meetings between BNFL and RU technical staffs typically begin one month or earlier before each Topical Meeting to identify issues and to develop the topic to the extent necessary for adequate coverage in the PSAR. This preparation is in consonance with the SER recommendation, and includes the BNFL suggestion to address and resolve issues in advance. The initial Topical Meeting protocol requires a working level meeting two weeks prior to the Topical Meeting. However, the RU may hold the working level meeting earlier, or meet several times, if necessary. Unsatisfactory Topical Meetings have resulted from lack of preparation on BNFL's part, rather than from an unwillingness of the RU to resolve issues in advance. Since revising the schedule in May, the quality of Topical Meetings has improved. However, with the new schedule, the discussion of major PSAR subjects has been extended through June 2000. That new schedule results in a major challenge for BNFL to complete the PSAR within five months of the conclusion of Topical Meetings.

SER Recommendation # 6. *The Regulatory Official should consider whether sufficient closure has been reached on seismic design requirements in the Topical Meetings and generally define the scope of such meetings versus that of the CAR review.*

RU Disposition: Closure has been nearly reached concerning seismic design requirements (including earthquake dose analysis requirements). Topical Meetings have not addressed actual seismic design features. (Although BNFL has included a limited amount of design feature information in their presentations, it was neither requested nor sufficient to be evaluated). The purpose of the Topicals has been, and remains, to resolve the requirements for seismic design and earthquake dose analysis prior to submission of the CAR.

Three Topical Meetings have occurred, or are planned, related to seismic design. The first, in December 1998, concerned the appropriate peak ground acceleration to use for the facility design. Agreement has been reached on this issue, and there are no outstanding items from this meeting.

The second, in June 1999, concerned the proposed tailoring of the seismic design standards (principally DOE-STD-1020) to be used for the facility. Agreement has been reached on these standards.

The last meeting, scheduled for one-half of the October 1999 Topical, will concern methods to assure that the facility as seismically designed, also has sufficient robustness to meet the separate (and independent) accident dose standards in the event of an earthquake. These dose standards are intended to ensure that no person receives an excessive exposure from any credible accident. (Design to meet DOE-STD-1020 does not directly address these considerations.)

In addition to the last Topical, another meeting is planned to facilitate resolution of the above issue. BNFL initially proposed to perform a seismic probabilistic risk assessment, then withdrew that proposal as too costly. They then proposed a seismic margin study as a less costly alternative. To further simplify resolution of this issue, the RU has clarified the acceptable methods of meeting the accident dose standards. As of October 13, 1999, BNFL was reevaluating its latest proposal, in preparation for the Topical Meeting on October 26, 1999. It is anticipated that this issue will be resolved then, or shortly thereafter.

To date, actual seismic design features have not been proposed by BNFL. The Topical Meetings and associated staff work have been constructive and productive, and have served as an efficient means to clearly establish the specific seismic design requirements prior to the submission of the CAR.

SER Recommendation # 7. *The Regulatory Official should consider whether or how to perform the quantitative reconciliation. The potential effects on seismic design of such a reconciliation, if performed, should be determined before the BNFL design freeze during Part B-1, which BNFL stated will be in January 2000.*

RU Disposition: Adequate safety for this project includes conforming with all of the top-level standards and principles established in DOE/RL-96-0006, *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors.* The authorization basis requirements of Table 2-1 of the SRD flow from Table 1 of DOE/RL-96-0006, and are risk-based dose standards. These dose standards are intended to ensure that no person receives an excessive exposure from a credible accident, including an extremely unlikely (but credible) earthquake. Credible accidents include some earthquakes less frequent than every 2000 years, the anchor frequency for the specific design criteria in DOE-STD-1020-94. If the extremely unlikely, but credible, earthquake should occur, the design will be acceptable, provided that the accident dose guidelines are not exceeded.

In contrast, the design of the facility to meet DOE-STD-1020-94 will ensure that there is very little damage to important to safety structures, systems, and components if an earthquake of the postulated 2000 year intensity should occur. The inclusion of this standard in the BNFL authorization basis implements the DOE/RL-96-0006 Standard 4.2.2.2, requiring design provisions to limit the loss of safety functions due to a common cause failure (such as an earthquake). Thus the two standards have different acceptance criteria, and are not, per se, inconsistent. Achieving a firm safety basis for the facility requires meeting both requirements.

To do this, it is incumbent upon BNFL to show that the facility designed to DOE-STD-1020-94 (as tailored by BNFL) has sufficient robustness to also meet the dose standards. If there are certain structures, systems, or components (SSCs) that are not robust enough to ensure the dose standards are met, reinforcement of those SSCs is appropriate.

In response to BNFL's request to eliminate the requirement to meet the dose standards for the entire extremely unlikely accident range, the RU issued a detailed interpretation of Table 2.1 on October 5, 1999, to deny this request, and to further explain what would be required to comply with Table 2-1. The key elements of this interpretation are that the dose standards must be met on average across the range from 10^{-4} to 10^{-6} accidents per year, best estimates (rather than bounding values) may be used for dose consequence modeling for extremely unlikely events, and a simplified performance model of the facility (rather than a component-level PRA) may be used. This interpretation provides BNFL with maximum flexibility while maintaining the fundamental requirements.

BNFL and the RU are currently scheduled to meet twice more on this subject in order to reach resolution in late October.

SER Recommendation # 8. *The Regulatory Official should assure that there is advance agreement between the RU and BNFL regarding the safety considerations to be addressed during the Design Reviews and that such agreements recognize the state of design completion.*

RU Disposition: In accordance with the TWRS-P Contract, the RU may observe design reviews and question the presenters. As observers, the RU should not obtain advance agreement regarding design review scope. Design reviews are BNFL meetings, and the process of obtaining advanced agreement could inappropriately influence the scope of their meetings. The RU acknowledges that some of the questions regarding safety features raised by RU staff and consultants were not appropriate for the design review observed by the SER. The RU is working to gain access to the BNFL safety review meetings in order to obtain information regarding safety features of the design as it evolves.

The RU maintains current information on the evolving design from design review oversight, but minimal information concerning ongoing hazard analysis and selection of safety features. The RU is working with BNFL to identify the proper forum to obtain insight into ongoing hazard analysis required to have confidence that the Construction Authorization Request will be approvable.

SER Recommendation # 9. *The Regulatory Official should assure that the proactive Inspection program planned is appropriate for the nature and pace of work being performed by BNFL.*

RU Disposition: The Regulatory Official continues to ensure that the proactive inspection program is carefully planned and appropriate for the nature and pace of work being performed by BNFL. The RU has actively sought out BNFL feedback in the

development and implementation of its inspection program. That feedback has been obtained in several important ways. First, BNFL was asked to review the RU Inspection Program Description (IPD) for the design phase to certify that the program did not result in additional contract cost. A similar request was made for review of the Limited Construction Authorization (LCA) phase revision to the IPD, and this process will be repeated for future phases of the program. Second, after BNFL certified the IPD revision, the RU issued, and made publicly available, the Inspection Program Implementation Plan (IPIP) and detailed technical inspection procedures (issued at least three months prior to use) for each of the 11 design-phase inspection areas. As they were issued by the RU, these inspection procedures were available for BNFL comment. Third, the RU developed and shared with BNFL, a copy of the initial and subsequent proposed inspection schedules. Several meetings with BNFL occurred to discuss the inspection schedule and BNFL's approach to ensuring appropriate implementation of its regulatory commitments. A number of changes were made to the inspection schedule in an attempt to address BNFL concerns regarding the potential RU impact, and to allow BNFL time to address its implementation problems.

Although RU design-phase inspection procedures were written to permit inspection of programmatic and implementation aspects of 11 design-related areas, the RU adjusted its inspection plans to account for the lack of BNFL's full implementation of its design programs (nearly all design work to date has resulted in preliminary, unapproved facility lay-out drawings and other draft documents). Consequently, the inspections to date have focussed on program reviews, and implementation of these programs has been somewhat limited. In order to provide meaningful input to the LCA and Construction Authorization (CA) approvals, the RU will perform at least a second round of design-phase inspections. These inspections will be performed prior to the scheduled dates for the authorization approvals (LCA -- August 2000, CA -- June 2001). In addition, to support the CA approval, the RU will conduct LCA inspections while continuing the design-phase inspections between August 2000 and June 2001. However, the RU will continue to adjust its inspection schedule to correlate with BNFL progress in the design and limited construction of their facility.

In summary, the RU will continue to work closely with BNFL in the implementation of the inspection program. The inspection program was developed based on regulatory requirements and current contractor schedules. Changes to the inspection schedule will continue as a result of BNFL requests, when properly warranted. The inspection program is sufficiently flexible to accommodate the pace of BNFL progress in any given area.

SER Recommendation # 10. *The RU should continue to take advantage of NRC support in the CAR review, gaining the benefit of independent peer review as well as experience.*

RU Disposition: The Regulatory Unit finds the NRC review of the contractor's submittals valuable, both from a technical review standpoint and as an independent peer review. The Regulatory Unit intends to revise the *Memorandum of Understanding* (MOU) at a time suitable to the NRC. The MOU requires revision due to the change in

scope of the privatization project (from pilot facility to full-scale production plant) and the Department's change in position on the potential for external regulation. The Regulatory Unit expects, as a minimum, to continue receiving NRC support through Construction Authorization. This intent was expressed in a December 23, 1998, letter from the RL Manager to Dr. Carl J. Paperiello, Director of the Office of Nuclear Material Safety and Safeguards, NRC.

SER Recommendation # 11. *To assure the timely execution of the RPP-P Project, DOE should seek an agreement with NRC that its staff will review the CAR according to the provisions of the RU regulatory system and the CAR Review Guidance, rather than NUREG-1702, where applicable differences exist.*

RU Disposition: As stated above (in the disposition of SER Recommendation # 10), the Regulatory Unit intends to revise the *Memorandum of Understanding* (MOU) at a time suitable to the NRC. As part of the revision, the Regulatory Unit plans to state that NRC should evaluate contractor submittals against RU review guidance and requirements, as well as NRC requirements.